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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,454	09/26/2006	Michael Kretschmar	LNK-021	9476

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,454	KRETSCHMAR ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/26/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed September 26, 2006, claims 1-9, 11-17 and 21-24 have been amended, and claims 18-20 have been cancelled. Therefore, claims 1-17 and 21-24 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-17 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-17 and 23-24 are indefinite because of the use of the terms "high activity", "low activity", "high specific VWF activity", "high specific activity", "low specific activity", and/or "relatively high salt concentration". The terms cited render the claim indefinite, it is not clear what are the metes and bounds for the activity, the specific activity or the concentration since all these terms are relative terms. Claims 3-21 and 23-24 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

4. Claim 24 is indefinite because the claims lack an essential step in the method of treating von Willebrand syndrome. The omitted step is an effective amounts of the composition administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 6, 11 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorman *et al.* (Thrombosis Research 12, 341-352 (1978); cited in IDS filed 9/26/2006).

Gorman *et al.* teach factor VIIIc fractions obtained from precipitation from plasma and gel filtration on Sepharose 6B, contain factor VIII coagulant activity, ristocetin cofactor activity and factor VIII R-ag activity (also termed VIII related antigen or von Willebrand factor; Fig. 1; Table 1). These fractions were pooled and further applied on hydroxylapatite chromatography equilibrated with 0.1 M NaCl, 5 mM potassium phosphate buffer (pH 6.8), the column was washed with equilibrating buffer, and factor VIII eluted with a 0.1 M potassium phosphate buffer (pH 6.8) in 0.1 M NaCl, in which VIII R-ag activity was also found (page 342-345; Fig. 2). Since Gorman *et al.* teach purifying the fractions containing von Willebrand factor using the same hydroxylapatite chromatography eluted with the same buffer and pH, which meet the criteria of the claimed method of claims 1-3, 5, 6, 11 and 21.

6. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnouf-Radosevich *et al.* (Vox Sanguinis 62, 1-11 (1992), cited in IDS filed 9/26/2006).

Burnouf-Radosevich *et al.* teach a therapeutic highly purified von Willebrand factor (vWF) concentrate with vWF specific activity (CBA) of 345 U/mg has been prepared from cryoprecipitate by a three-step chromatographic procedure (i.e., first DEAE-fractogel; second

DEAE-fractogel; and gelatin-Sepharose), and clinical use of this standardized vWF concentrate has been shown to be efficacious in the treatment of vWF patients (abstract; page 4, Fig. 1, Tables 1 and 2; page 10). Since the vWF composition taught by Burnouf-Radosevich *et al.* has high vWF specific activity (CBA) of 345 U/mg (at least 120 U/mg) and can be used to treat vWF syndrome, thus, the vWF composition of Burnouf-Radosevich *et al.* is not different from the claimed vWF composition, which meets the criteria of claims 21-24. The patentability of a product does not depend on the method of production, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (see MPEP 2113).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-17 and 21-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 22-23 of co-pending application 10/594,455 (based on preliminary amendment filed 9/26/2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-17 and 21-23 in the instant application discloses a method of separating a vWF having a

high activity from a vWF having a low activity, producing a composition having a high specific vWF activity, or raising the specific vWF activity of a vWF containing composition by the step of purifying a vWF composition with hydroxyapatic chromatography; and a vWF composition purified by the process. This is obvious variation in view of claims 1-20 and 22-23 of the co-pending which discloses a method of purifying vWF by carrying out at least one hydroxyapatite chromatography, and the method may further use a separate hydroxyapatite chromatography to bind vFW and then the vFW is eluted; and a vWF composition purified by the process. Both the claims of instant application and the claims of the co-pending application are directed to a method of purifying vWF by carrying out at least one hydroxyapatite chromatography, and the method may further use a separate hydroxyapatite chromatography to bind vFW and then the vFW is eluted; and a vWF composition purified by the process. Thus, claims 1-17 and 21-23 in present application and claims 1-20 and 22-23 of the co-pending are obvious variations of a method of purifying vWF by carrying out at least one hydroxyapatite chromatography, and the method may further use a separate hydroxyapatite chromatography to bind vFW and then the vFW is eluted; and a vWF composition purified by the process.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
January 16, 2009